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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
YARNALL, MEGAN LEIGH	
ART UNIT	**PAPER NUMBER**
3738	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/519,338	LERF, RETO	
	Examiner	Art Unit	
	MEGAN YARNALL	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *012808*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 1/28/08 have been fully considered but they are not persuasive. Because claim 1 has been amended to include the limitations of claim 3, only the previous rejection of claim 3 will be discussed. First note that Pilliar does teach an open-pored structure of the claimed porosity and thickness. The fact that the pores are open to the surface and are able to allow bony ingrowth makes them “open-pored". Applicant argues that Steinemann 5,456,723 does not include a porous surface as well as a roughening in the sub-micrometer range. The Examiner disagrees with Applicant's interpretation of Steinemann. Steinemann discloses a porous surface with sub-micron roughness in col.3, ll.1-5. It is well known in the art to use porous implants for bony ingrowth (for example Steinemann suggests the use of tantalum which is a well known porous implant material) but Steinemann teaches that the addition of micro-roughness to the surface improves the adhesion between bone and implant. Therefore, the combination of the details of the porosity of the surface disclosed by Pilliar and the features of a sub-micrometer surface roughness obviates claim 3 and amended claim 1.

2. Applicant argues that the rejection of claim 8 which is anticipated by Pilliar 3,855,638 is improper because Pilliar does not teach a surface micro-structure less than 50 μm, but this limitation is not stated in claim 8. Claim 8 simply states applying at least one layer of a biocompatible metal or an alloy thereof to a virgin surface of the implant to produce an implant surface comprising an open-pored structure with a porosity in a range of between about 20% and 85%, and producing a surface micro-structure.

Therefore, the micro-sized surface pores disclosed by Pilliar may be considered the surface micro-structure on the implant surface. Similarly with respect to the rejection of claim 8 over Shimamune 5,034,186, Applicant argues that the process in Shimamune produces only one level of structure, and therefore doesn't produce both an open-pored structure and a surface micro-structure. However, as the claim is written, the open-pored structure comprising micro-sized surface pores may be considered the surface microstructure. Claim 8 does not adequately distinguish the two levels to overcome the rejection over either Pilliar or Shimamune.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 23, 24, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 23 and 24 recite the limitation "the fine biocompatible particles" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 36 recites the limitation "the biocompatible particles" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 8, 10-12, 15-20, 24, 25, 29, 30, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Pilliar 3,855,638. Pilliar discloses a method of producing an implant comprising applying at least one layer of a biocompatible metal or an alloy thereof to a surface of the implant, to produce an implant surface comprising an open-pored structure with a porosity in a range of between about 20% and 85% (col.8, ll.9-38; col.11, ll.1-2) and producing a surface micro-structure (the micro sized pores) on the implant surface (col.4, ll.17-20).

9. Re claims 10 and 11, see col.8, ll.57-60.

10. Re claim 12, see col.7, ll.29-32.

11. Re claim 15, see col.7, ll.37-40.

12. Re claim 16, see col.7, ll.49-51.

13. Re claim 17, see col.4, ll.38-40.

14. Re claim 18, see col.4, ll.21-33.

15. Re claim 19, see col.7, l.47.

16. Re claim 20, see col.2, ll.65-67.

17. Re claims 24, 25, and 32, see col.7, ll.29-32.

18. Re claims 29 and 30, see col.8, ll.9-38.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 8, 11-14, 22, 23, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimamune 5,034,186. Shimamune teaches a method of producing an implant comprising applying at least one layer of a biocompatible metal or an alloy thereof to a surface of the implant to produce an implant surface and producing a surface micro-structure on the implant surface (col.1, l.59-col.2, l.2, and col.4, ll.55-57). Shimamune also discloses that a binder may be used in a volume ration of 5-75% which means that the final sintered product, upon removal of the binder, will have a porosity of approximately 5-75%. Still, it has been held that it is not inventive to discover the optimum or workable ranges by routine experimentation and would be an obvious extension of prior art teachings (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A).

21. Re claim 11, Shimamune further teaches a method wherein the at least one layer applied to the virgin surface of the implant is sintered (col.3, l.9).

22. Re claim 12, Shimamune further teaches a method wherein materials are selected from the group consisting of binders, and sintering adjuvants (col.2, l.67).

23. Re claim 13, Shimamune further teaches a method wherein as sintering adjuvant there is used a sintering adjuvant metal (col.2, ll.27-28) which, together with the biocompatible metal or alloy thereof, forms a low-melting eutectic (col.2, ll.28-44).

24. Re claim 14, Shimamune further teaches a method wherein sintering is carried out in vacuo (col.1, ll.66-68).

25. Re claims 22 and 31, Shimamune further teaches a method wherein surface micro-structure is produced by etching of the implant surface (col.2, l.20) by means of acid bath etching (col.3, ll.21-30).

26. Re claim 23, Shimamune further teaches a method wherein the fine biocompatible particles have a particle size in a range from 0.01μm to 5μm (col.4, ll.15-17).

27. Claims 1, 2, 6, 7, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pilliar 3,855,638 in view of Steinemann et al. 5,456,723. Pilliar teaches the invention substantially as claimed including an open-pored surface layer with a thickness in a range from 0.1mm to 2.5mm inclusive (col.4, ll.21-33) and the porosity of the open-pored surface layer in a range from 20% to 80% (col.11, ll.1-2). However, Pilliar does not disclose that the open pored layer further comprise a shallow roughening in the sub-micrometer range.

28. Steinemann teaches a metallic implant, in the same field of endeavor, comprising a porous surface with a surface roughness of 2μm or less (col.3, ll.1-5 and 23-25), for the purpose of improving the interface between bone and implant such that bone readily grows into the implant and the bond between the implant and bone is capable of resisting all of the mechanical forces it will be exposed to during it's use (col.2, ll.45-50).

29. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the porous coating disclosed by Pilliar in view of the sub-micrometer surface roughness taught by Steinemann in order to make the mating bone

grow with the implant along the contact surface and quickly form a strong and durable bond as taught by Steinemann, col.3, ll.20-23.

30. Re claim 2, Steinemann teaches pits having a diameter of 2μm or less (col.3, ll.23-25).

31. Re claim 6, see Pilliar col.2, ll.65-67 and Steinemann claim 5.

32. Re claim 7, see Pilliar col.8, ll.33-36.

33. Re claims 26-28, see col.5, ll.38-40 for the intended use of the device which is given little patentable weight.

34. Claims 1, 4, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimamune 5,034,186 in view of Steinemann et al. 5,456,723. Shimamune teaches a porous surface layer with a thickness in a range from 0.1mm to 2.5mm inclusive (col.4, ll.30-32). Shimamune further discloses that a binder may be used in a volume ration of 5-75% which means that the final sintered product, upon removal of the binder, will have a porosity of approximately 5-75%. Further, it has been held that it is not inventive to discover the optimum or workable ranges by routine experimentation and would be an obvious extension of prior art teachings (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A). Shimamune further discloses that the particle size of the material forming the porous layer may be anywhere from several microns to several millimeters depending on the specific use of the product (col.2, ll.54-55), but does not specifically disclose a roughening in the sub-micrometer range.

35. Steinemann teaches a metallic implant, in the same field of endeavor, comprising a porous surface with a surface roughness of 2μm or less (col.3, ll.1-5 and 23-25), for the purpose of improving the interface between bone and implant such that bone readily grows into the implant and the bond between the implant and bone is capable of resisting all of the mechanical forces it will be exposed to during it's use (col.2, ll.45-50).

36. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the porous coating disclosed by Shimamune in view of the sub-micrometer surface roughness taught by Steinemann in order to make the mating bone grow with the implant along the contact surface and quickly form a strong and durable bond as taught by Steinemann, col.3, ll.20-23.

37. Re claims 4 and 5, see Shimamune col.2, ll.51-58.

38. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shimamune 5,034,186 in view of Shimp 2001/0031799. Shimamune teaches the invention substantially as claimed. However, Shimamune does not teach a method wherein the biocompatible metal is applied by means of a vacuum plasma spraying method.

39. Shimp teaches a coating applied to an implant, in the same field of endeavor, by means of a vacuum plasma spraying method (par.13, l.7), for the purpose of very fast heating and cooling (par.13, 14).

40. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Shimamune where the biocompatible metal may be sprayed on (Shimamune col.3, ll.1-5) in view of the vacuum plasma spraying

method taught by Shimp in order to produce very fast heating or cooling as taught by Shimp, par.13, l.4.

41. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pilliar 3,855,638 in view of Pilliar 4,206,516. Pilliar teaches the invention substantially as claimed. However, Pilliar '638 does not teach a method wherein the biocompatible metal is used in the form of a metal hydride powder.

42. Pilliar '516 teaches a method of making a coating, in the same field of endeavor, wherein the biocompatible metal is used in the form of a metal hydride powder (col.2, ll.46-49), for the purpose of providing a thermally decomposable compound (col.2, ll.50-51).

43. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Pilliar '638 in view of Pilliar '516 in order to provide a thermally decomposable compound as taught by Pilliar '516, col.2, ll.50-51.

44. Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. 5,843,298.

45. Lee discloses an open-pored coated implant comprising a surface of at least one layer of biocompatible metal with a surface micro-structure applied to the open-pored implant surface, the microstructure comprising pits having a diameter in a range from 0.01-5 μm (col.7, l.66-col.8, l.12). While Lee does not specifically disclose that the porosity of the open-pored surface is in a range from 20-85%, it has been held that it is not inventive to discover the optimum or workable ranges by routine experimentation and would be an obvious extension of prior art teachings (In re Aller, 220 F.2d 454, 456,

105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A). Regarding the process of applying the surface microstructure via a vacuum plasma spraying process, the method by which the product is made is not germane to the issue of patentability of the product itself and is not given patentable weight.

46. Re claims 38 and 39, see col.8, ll.13-25.

47. Re claim 40, see col.7, ll.16-21.

48. Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowe et al. 4,542,539 in view of Steinemann et al. 5,456,723. Rowe discloses the invention substantially as claimed including applying at least one layer of a biocompatible metal or an alloy thereof to a virgin surface of an implant to produce an open-pored implant surface (figs. 1-4) wherein the open-pored implant surface is produced by a plasma spraying method (col.5, ll.45-48) and wherein the surface may be roughened slightly if desired (col.6, ll.5-6). However, Rowe does not specifically disclose that the roughening is a micro-structure.

49. Steinemann teaches a metallic implant, in the same field of endeavor, comprising a porous surface with a surface roughness of 2μm or less (col.3, ll.1-5 and 23-25), for the purpose of improving the interface between bone and implant such that bone readily grows into the implant and the bond between the implant and bone is capable of resisting all of the mechanical forces it will be exposed to during it's use (col.2, ll.45-50).

50. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the porous coating disclosed by Rowe in view of the micro-structure on the porous surface taught by Steinemann in order to make the mating bone

grow with the implant along the contact surface and quickly form a strong and durable bond as taught by Steinemann, col.3, ll.20-23.

51. Re claims 34 and 35, see figs. 1-3.

52. Re claim 36, Rowe discloses that biocompatible particles are applied via plasma spraying but does not specifically disclose the particle size range. However, it has been held that it is not inventive to discover the optimum or workable ranges by routine experimentation and would be an obvious extension of prior art teachings (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A).

Conclusion

53. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEGAN YARNALL whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 7:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. Y./
Examiner, Art Unit 3738
4/7/08

/Bruce E Snow/
Primary Examiner, Art Unit 3738